

1. Claims 6 through 12 and 14 through 20 are pending. Claim 13 has been canceled. Applicant's claim to priority from provisional application 60/487,982 filed July 17, 2003 is acknowledged. Applicants' amendments and arguments filed August 8, 2008, as well as the Information Disclosure Statement (IDS) filed July 10, 2008 have been entered and carefully considered.

***Reasons for Allowance***

2. With regard to the prior rejection of claims 6 through 14 under the first paragraph of 35 U.S.C. 112, Applicants have canceled claim 13 and argue that the specification is enabling for the claimed methods of inhibiting the binding of acetylcholine to an acetylcholine receptor and more specifically an acetylcholine receptor in the respiratory tract comprising the  $M_3$  muscarinic acetylcholine receptor in both cases in a mammal in need thereof, wherein in both cases the compound used is administered to said mammal as a dry powder by inhalation by the mouth of said mammal. Applicants' arguments have been found to be persuasive. The compounds of Formula (I) are enabled for anti-cholinergic activity by Zirkle (US 2,800,481), and the specification outlines the *in vitro* and *in vivo* assays used to assess binding of muscarinic antagonists to the  $M_3$  muscarinic acetylcholine receptor, and the potency and duration of action in the mammalian tracheae. Therefore, the rejection of claims 6 through 12 and 14 as lacking enablement is hereby withdrawn.

3. The claimed subject matter is neither anticipated by, nor obvious over, the prior art.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David E. Gallis whose telephone number is 571-272-9068. The examiner can normally be reached on Mon-Thur 8:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David E. Gallis  
Patent Examiner

/ Bernard Dentz/

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